REMARKS

Reconsideration and withdrawal of the rejections set forth in the Office action dated March 14, 2005 are respectfully requested.

I. Amendments

Claims 1 and 6 are amended to clarify the positioning of the recited structures.

Claim 7 is amended to depend from claim 6.

Claim 15 is amended to recite at least the reagent pad is formed of an asymmetric polysulfone membrane.

Claim 17 is amended for proper antecedent basis.

Claim 23 is amended to recite a sample reservoir containing the sample.

Claim 24 is amended for proper antecedent basis.

New claim 31 finds basis in original claim 15.

No new subject matter is added by way of these amendments.

II. Rejection under 35 U.S.C. §112, second paragraph

Claims 1-10 were rejected under 35 U.S.C. §112, second paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. The Examiner had six specific objections, which are set forth and discussed below.

1. Claim 1

The Examiner objected claim 1 as allegedly indefinite and incomplete. Specifically, the Examiner alleges the structural relationship between the sample distribution array and both the HDL test pad and reagent pad is not clear. Applicant's amended claim clarifies the structural relationship of the elements.

2. Claim 6

The Examiner objected to claim 6 as allegedly unclear where in the device the sieving pad is located in relation to the sample distribution array, HDL test pad and reagent pad.

Claim 6 is amended to recite the relationship of the sieving pad in relation to the surrounding structure.

3. Claim 7

The Examiner objected to the language "said sieving pad" allegedly for antecedent basis.

Claim 7 is amended to depend from claim 6, which recites a sieving pad.

4. Claim 15

The Examiner objected to claim 15 as allegedly unclear whether both the reagent pad and HDL pad are formed of an asymmetric polysulfone membrane or whether only one of the reagent pad or HDL test pad are formed of an asymmetric polysulfone membrane.

Claim 15 is amended to clarify that at least the reagent pad is formed of an asymmetric polysulfone membrane.

5. Claim 17

The Examiner objected to the language "said HDL test pad" as allegedly lacking antecedent basis.

Claim 17 is amended to recite "an HDL test pad."

6. Claim 24

The Examiner objected to the language "said sieving pad" and "said sample distribution pad" as allegedly lacking antecedent basis.

Claim 24 is amended to recite the "reservoir" and "laminate" as described in claim 23.

In light of the above amendments, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §112, second paragraph.

III. Rejections under 35 U.S.C. §102

Claims 1, 5-14 and 23-30 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by Jones *et al.* (US 2003/0224471, hereinafter "the '471 application").

Claims 1, 5-14 and 23-30 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by Jones *et al.* (US 2003/0166291, hereinafter "the '291 application").

These rejections are respectfully traversed for the following reasons.

A. The Invention

The present invention relates to an assay device and method for measuring serum cholesterol associated with high-density lipoproteins (HDL) in a blood fluid sample containing lipoproteins other than HDLs.

The device includes a HDL test pad in which HDL concentration can be assayed being spaced apart from a sample distribution array and being affixed to a mounting means; and a reagent pad containing a binding reagent effective to selectively bind and remove non-HDLs from the fluid sample, where the HDL test pad and the reagent pad are joined. The mounting means are effective (i) to maintain the device in a sample-distribution position, wherein the joined HDL test pad and reagent pad are spaced apart from the array, and (ii) to transfer the device to a test position, whereby the joined HDL test pad and reagent pad are in contact with the array.

The method of claim 23 includes the step of contacting a sample reservoir containing a blood fluid sample with a laminate comprising (i) an HDL test pad having a detectable indicator of HDL cholesterol, (ii) a reagent pad containing a reagent effective to selectively bind and remove non-HDLs from the fluid sample, wherein the blood fluid sample passes through the laminate by capillary action and/or gravity through the laminate to permit measurement of HDL concentration.

The method of claim 15 includes providing a reagent pad and an HDL test pad, heating to adhere the pads, and applying appropriate reagents to the HDL test pad and the reagent pad.

The method of claim 17 includes coating a reagent pad with an acrylic acid copolymer, applying appropriate reagents to the reagent pad and a HDL test pad, and heating to adhere the pads.

B. The Cited Art

THE '471 APPLICATION Under M.P.E.P. § 2136.05, a 35 U.S.C. 102(e) rejection can be overcome by showing the reference is describing the applicant's own work. Such a showing may be met by a Declaration under 37 C.F.R. § 1.132 by the applicant stating that he/she conceived or invented the subject matter disclosed in the patent or application publication and relied on in the rejection (*In re DeBaun*, 687 F.2d 459, 214 USPQ 933 (CCPA 1982)).

Applicant encloses herewith such a Declaration under 37 C.F.R. § 1.132 by Ronald M. Jones who is the sole inventor on the present application as well as a named inventor of the '471 application. Accordingly, Applicant submits that the '471 application is not an effective document under 35 U.S.C. § 102(e).

THE '291 APPLICATION Applicant encloses herewith a Declaration under 37 C.F.R. § 1.132 by Ronald M. Jones who is the sole inventor on the present application as well as a named inventor of the '291 application stating he conceived or invented the subject matter disclosed in the '291 application and relied on in the rejection. Accordingly, Applicant submit that the '291 application is not an effective document under 35 U.S.C. § 102 or § 103.

In view of the above, withdrawal of the rejections under 35 U.S.C. §102(e) is respectfully requested.

IV. Rejections under 35 U.S.C. §103

Claims 2-4 and 15-22 were rejected under 35 U.S.C. §103 as allegedly obvious over the '291 application in view of both Kitani *et al.* and Ditter *et al.*

These rejections are respectfully traversed.

A. The Present Invention

The present invention is described above.

B. The Prior Art

THE '291 APPLICATION In view of the Declaration under 37 C.F.R. § 1.132 by Ronald M. Jones, the '291 application is not an effective document under 35 U.S.C. § 102 or § 103.

KITANI ET AL. relate to a dry analysis element for the quantitative analysis of an analyte contained in whole blood comprising, as an integrally laminated layer, a micro-fibrous cloth and a detection layer. The micro-fibrous cloth separates blood cells and blood plasma without hemolysis. In a preferred embodiment, a volume filtrating layer is laminated with a porous layer and partially bound with spot-bonding (Col. 6, lines 64-67) arranged partially or discontinuously on the interface so as not to hinder uniform passage of a liquid through and between the layers (Col. 11, lines 27-31).

DITTER ET AL. relate to composite filter laminates composed of multiple discrete layers of material bonded together.

C. Analysis

According to M.P.E.P. § 2143, "to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings.

Second, there must be a reasonable expectation of success. Third, the prior art references (or references when combined) must teach or suggest all the claim limitations."

As noted above, the '291 application is not prior art with respect to the current claims and cannot be combined with the Kitani *et al.* and Ditter *et al.* references.

The present claims and method disclose an assay and method for measuring the concentration of HDL-associated cholesterol in a sample. The present claims further disclose methods for preparing the device. As noted above, the device includes a sample distribution array and a HDL test pad, in which HDL concentration can be assayed, joined to a reagent pad containing a binding reagent effective to selectively bind and remove non-HDLs from the fluid sample. In operation, the joined HDL test pad and reagent pad are not in fluid communication with the sample distribution array in a sample distribution stage. When the blood sample reaches the one or more sample collection regions, the device is adjusted to a test position to place the joined HDL test pad and reagent pad in fluid communication with the sample distribution array. In this position, sample fluid in the sample distribution array is drawn into the reagent pad by capillary flow. The sample fluid is further drawn into the HDL test pad(s) by capillary flow. The device is held at this position until a desired degree of wetting of the test pad(s) is achieved. The device is then moved, if desired, to break fluid communication between the sample distribution array and the joined HDL test pad and reagent pad, when a desired amount of sample fluid has entered the assay pad(s), and/or after an appropriate contact time.

Neither of the cited Kitani *et al.* or Ditter *et al.* references disclose this advantageous configuration. Kitani *et al.* are concerned with a dry analysis element including an integrally laminated layer a micro-fibrous cloth. Ditter *et al.* describe a composite filter laminate. Neither reference make any mention of a device or methods as presently claimed.

Because neither reference, taken alone or in combination, show or suggest an assay device or method for measuring serum cholesterol associated with high-density lipoproteins (HDL) in a blood fluid sample containing lipoproteins other than HDLs as presently claimed the standard for obviousness has not been met. Accordingly, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §103.

V. Conclusion

In view of the foregoing, Applicant submits that the claims pending in the application are in condition for allowance. A Notice of Allowance is therefore respectfully requested.

If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 838-4410.

Respectfully submitted,

Jacqueline F. Mahoney

Date: June 14, 2005

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Attorney Docket No. 52325-8019.US00

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Ronald M. Jones	EXAMINER: Wallenhorst
SERIAL NO.: 10/816,557	ART UNIT: 1743
FILED: April 1, 2004	CONFIRMATION NO.: 1236
FOR: **ADHERED MEMBRANES RETAINING POROSITY AND BIOLOGICAL ACTIVITY**	

Declaration Under 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Ronald M. Jones, declare and affirm as follows:

1. I am the sole inventor of the subject matter described and claimed in U.S. Patent Application Serial No. 10/816,557, filed April 1, 2004, entitled ADHERED MEMBRANES RETAINING POROSITY AND BIOLOGICAL ACTIVITY.

2. I am a co-inventor of US application no. 10/410,671 filed April 8, 2003 and published December 4, 2003 as US 2003/0224471, entitled HIGH-DENSITY LIPOPROTEIN ASSAY DEVICE AND METHOD (hereinafter "the '471 application"). The application includes as co-inventors Thomas E. Worthy, Jeffrey Shindelman, Neal F. Bellet, and Anthony J. Nugent.

3. The '471 application discloses a multiple analyte assay device and method for measuring the concentration of HDL-associated cholesterol in a blood-fluid sample. The device includes a main body that defines a well for receiving the blood sample.

The well is in fluid communication with a sieving pad, which functions to remove large particulate matter from the blood sample. The sieving pad contacts a sample distribution matrix to distribute sample fluid to sample-collection regions (see paragraphs 0049 and 0050-0051). A reaction bar includes multiple reaction test pads used in a particular assay and containing analyte-dependent reagents, including an HDL test pad (see paragraph 0052). A reagent pad having immobilized thereto a reagent effective to bind and remove non-HDL lipoproteins may be provided between the sample distribution matrix and HDL test pad (see paragraph 0056).

4. As seen in Fig. 1, the reagent pad may be affixed to the HDL test pad (see paragraph 0056).

5. I hereby declare and affirm that I conceived the subject matter disclosed in the '471 application and relied on in the present rejection as described in point 4, above.

6. I am a co-inventor of US application no. 10/346,685 filed January 17, 2003 and published September 4, 2003 as US 2003/0166291, entitled HIGH-DENSITY LIPOPROTEIN ASSAY DEVICE AND METHOD (hereinafter "the '291 application"). The application includes as co-inventors Thomas E. Worthy and Anthony J. Nugent.

7. The '291 application discloses a multiple analyte assay device and method for measuring the concentration of HDL-associated cholesterol in a blood-fluid sample. The device includes a main body that defines a well for receiving the blood sample. The well is in fluid communication with a sieving pad, which functions to remove large particulate matter from the blood sample. The sieving pad contacts a sample distribution matrix to distribute sample fluid to sample-collection regions (see paragraphs 0050-0052). A reaction bar includes multiple reaction test pads used in a particular assay and containing analyte-dependent reagents, including an HDL assay element (see paragraph 0054). A reagent pad having immobilized thereto a reagent

effective to bind and remove non-HDL lipoproteins may be provided between the sample distribution matrix and HDL test pad (see paragraph 0059).

8. In one embodiment, the HDL assay element has affixed thereto a reagent pad (see paragraph 0058 and Fig. 1 and 3).

9. I hereby declare and affirm that I conceived the subject matter disclosed in the '291 application and relied on in the present rejection as described in point 8, above.

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the Unites States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

6/14/05
Date

Ronald M. Jones
Ronald M. Jones